

#7  
JW

Docket No.: B173CIP1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Thalia Papayannopoulou

SERIAL NO.: 08/436,339

FILED: July 13, 1995

FOR: PERIPHERALIZATION OF HEMATOPOIETIC STEM CELLS

GROUP ART UNIT: 1806

EXAMINER: Nancy A. Johnson

96 OCT 30 5:03 PM '96  
0700 100

Assistant Commissioner for Patents  
Washington, D.C. 20231

**RESPONSE**

Sir:

In an Office Action dated October 10, 1996, the Examiner has required restriction to one of the following inventions:

Group I: claims 1-14, drawn to a method of peripheralizing stem cells, classified in Class 424, subclass 144.1.

Group II: claims 15-18, drawn to a method of treating cancer, classified in Class 424, subclass 144.1.

Group III: claims 19-24, drawn to a method of treating AIDS, classified in Class 424, subclass 144.1.

Group IV: claims 25-28, drawn to a gene therapy method, classified in Class 424, subclass 93.1.

The Examiner has alleged that the methods of Groups I-IV differ in the method objectives, the method steps and parameters, and in the reagents used. Further, the Examiner alleges that the inventions are distinct for the "reasons given above" and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive.

Applicants provisionally elect the claims of Group I with traverse. Applicants respectfully submit that restriction in this application is improper because the Examiner has failed to establish that the inventions are independent and distinct, as required by 35 U.S.C. § 121. Specifically, the Examiner has merely stated that the methods, steps, parameters and reagents used are different, without indicating a basis why the claims in Groups I-IV are independent and distinct. Therefore, applicants request that the restriction requirement be withdrawn.

Additionally, the Examiner has indicated that the application contains sequence disclosures which do not comply with the sequence rules. However, this application is the national stage of international application PCT/US93/11060 filed November 15, 1993. The present application entered the national stage under 35 U.S.C. § 371 on May 12, 1995. Upon filing in the U.S. receiving office, applicants submitted a CRF copy of the sequence listing, a paper copy of the sequence listing, and computer readable copies of the same. For the Examiner's convenience, applicants have attached hereto a copy of the PCT transmittal papers indicating that the C.F.R. and appropriate documentation related to the sequence listing were enclosed. Therefore, applicants do not believe that resubmission of the CRF copy of the sequence listing and related documentation is required. If these documents have been misplaced or separated from the Examiner's files, kindly contact the undersigned and duplicates will be provided.

Applicants respectfully request prompt and favorable action on the merits of this application.

Dated: 10/23/96

Respectfully submitted,



Kerry A. Flynn  
Attorney for Applicant(s)  
Reg. No. 33,693  
Biogen, Inc.  
14 Cambridge Center  
Cambridge, MA 02142

**"EXPRESS MAIL"** mailing label number EM046583285US  
Date of Deposit October 23, 1996

I hereby certify that this paper/fee is being  
deposited with the United States Postal Service **"EXPRESS  
MAIL POST OFFICE TO ADDRESSEE"** service under **37 C.F.R. 1.10**  
on the date indicated above and is addressed to the Hon.  
Assistant Commissioner for Patents, Washington, D.C. 20231



IN THE UNITED STATES RECEIVING OFFICE  
OF THE PATENT COOPERATION TREATY

Applicants : Board of Regents of University of  
Washington et al.  
For : PERIPHERALIZATION OF HEMATOPOIETIC  
STEM CELLS  
Filed : Concurrently herewith  
15 November 1993

New York, New York  
15 November 1993

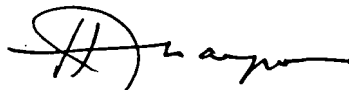
Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231  
Attention: RO/US

STATEMENT TO VERIFY CONTENT OF COMPUTER  
READABLE FORM SUBMISSION UNDER 37. C.F.R. § 1.821(f)

Sir:

I hereby state that the content of the paper  
and the computer readable copy of the Sequence Listing,  
submitted in the above-identified international  
application in accordance with 37 C.F.R. § 1.821(c) and  
(e), respectively, are the same.

Respectfully submitted,



---

Immac J. Thampoe (Reg. No. 36,322)  
Patent Agent for Applicants  
c/o FISH AND NEAVE  
1251 Avenue of the Americas  
New York, New York 10020  
Tel.: (212) 596-9000

# PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference

(if desired) (12 characters maximum)

B173 CIP PCT

### Box No. I TITLE OF INVENTION

PERIPHERALIZATION OF HEMATOPOIETIC STEM CELLS

### Box No. II APPLICANT

Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)

BOARD OF REGENTS OF UNIVERSITY  
OF WASHINGTON  
Office of Technology Transfer  
4225 Roosevelt Way, N.E., Suite #301  
Seattle, Washington 98105  
United States of America

☐ This person is also inventor.

Telephone No.

(206) 543-3970

Facsimile No.

(206) 685-4767

Teleprinter No.

--

State (i.e. country) of nationality:

United States of America

State (i.e. country) of residence:

United States of America

This person is applicant for the purposes of:

☐

all designated States

☒

all designated States except the United States of America

☐

the United States of America only

☐

the States indicated in the Supplemental Box

### Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS

Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)

PAPAYANNOPOULOU, Thalia  
3336 Cascadia Avenue South  
Seattle, Washington 98144  
United States of America

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

United States of America

State (i.e. country) of residence:

United States of America

This person is applicant for the purposes of:

☐

all designated States

☐

all designated States except the United States of America

☒

the United States of America only

☐

the States indicated in the Supplemental Box

Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)

This person is:

☐ applicant only

☐ applicant and inventor

☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

State (i.e. country) of residence:

This person is applicant for the purposes of:

☐

all designated States

☐

all designated States except the United States of America

☐

the United States of America only

☐

the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

**Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☒ agent ☐ common representative

Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)

HALEY, James F. Jr.  
THAMPOE, Immac J.  
c/o Fish & Neave  
1251 Avenue of the Americas  
New York, New York 10020  
United States of America

Telephone No.

(212) 596-9000

Facsimile No.

(212) 596-9090

Telex No.

14-8367

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

**Box No. V DESIGNATION OF STATES**

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

**Regional Patent**

☒ EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, DE Germany, DK Denmark, ES Spain, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☐ OA OAPI Patent: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Gabon, Guinea, Mali, Mauritania, Niger, Senegal, Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- |   |   |
|---|---|
| <input type="checkbox"/> AT Austria                               | <input type="checkbox"/> MN Mongolia                            |
| <input checked="" type="checkbox"/> AU Australia                  | <input type="checkbox"/> MW Malawi                              |
| <input type="checkbox"/> BB Barbados                              | <input type="checkbox"/> NL Netherlands                         |
| <input type="checkbox"/> BG Bulgaria                              | <input type="checkbox"/> NO Norway                              |
| <input type="checkbox"/> BR Brazil                                | <input checked="" type="checkbox"/> NZ New Zealand              |
| <input type="checkbox"/> BY Belarus                               | <input type="checkbox"/> PL Poland                              |
| <input checked="" type="checkbox"/> CA Canada                     | <input type="checkbox"/> PT Portugal                            |
| <input type="checkbox"/> CH and LI Switzerland and Liechtenstein  | <input type="checkbox"/> RO Romania                             |
| <input type="checkbox"/> CZ Czech Republic                        | <input type="checkbox"/> RU Russian Federation                  |
| <input type="checkbox"/> DE Germany                               | <input type="checkbox"/> SD Sudan                               |
| <input type="checkbox"/> DK Denmark                               | <input type="checkbox"/> SE Sweden                              |
| <input type="checkbox"/> ES Spain                                 | <input type="checkbox"/> SK Slovakia                            |
| <input type="checkbox"/> FI Finland                               | <input type="checkbox"/> UA Ukraine                             |
| <input type="checkbox"/> GB United Kingdom                        | <input checked="" type="checkbox"/> US United States of America |
| <input type="checkbox"/> HU Hungary                               | Continuation-in-Part  |
| <input checked="" type="checkbox"/> JP Japan                      | <input type="checkbox"/> VN Viet Nam                            |
| <input type="checkbox"/> KP Democratic People's Republic of Korea |   |
| <input type="checkbox"/> KR Republic of Korea                     |   |
| <input type="checkbox"/> KZ Kazakhstan                            |   |
| <input type="checkbox"/> LK Sri Lanka                             |   |
| <input type="checkbox"/> LU Luxembourg                            |   |
| <input type="checkbox"/> MG Madagascar                            |   |

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☐
- ☐
- ☐
- ☐

In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of \_\_\_\_\_  
The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

## Supplemental Box

If the Supplemental Box is not used, this sheet need not be included in the request.

Use this box in the following cases:

1. If, in any of the Boxes, the space is insufficient to furnish all the information:
  - in particular:
    - (i) if more than three persons are involved as applicants and/or inventors and no "continuation sheet" is available:
 

in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient;
    - (ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked:
 

in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State or States (and/or, where applicable, European or OAPI patent) for the purposes of which the named person is applicant;
    - (iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America:
 

in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State or States (and/or, where applicable, European or OAPI patent) for the purposes of which the named person is inventor;
    - (iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents:
 

in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;
    - (v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," "certificate of addition," or "inventor's certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "Continuation" or "Continuation-in-part":
 

in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;
    - (vi) if there are more than three earlier applications whose priority is claimed:
 

in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.
2. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerning non-prejudicial disclosures or exceptions to lack of novelty:
 

in such case, write "Statement Concerning Non-Prejudicial Disclosures or Exceptions to Lack of Novelty" and furnish that statement below.

Continuation of Box No. V

United States of America  
 application no. 07/977,702  
 filed 13 November 1992 (13.11.92)

**Box No. VI PRIORITY CLAIM**Further priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country (in which, or for which, the application was filed)	Filing Date (day/month/year)	Application No.	Office of filing (only for regional or international application)
item (1) US	13 November 1992 (13.11.92)	07/977,702	
item (2)			
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): (1)**Box No. VII EARLIER SEARCH**

Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request:

Country (or regional Office):

Date (day/month/year):

Number:

**Box No. VIII CHECK LIST**

This international application contains the following number of sheets:

1. request : 4 sheets
2. description : 43 sheets
3. claims : 5 sheets
4. abstract : 1 sheets
5. drawings : 10 sheets

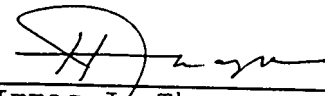
Total : 63 sheets

This international application is accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney
2. ☐ copy of general power of attorney
3. ☐ statement explaining lack of signature
4. ☐ priority document(s) identified in Box No. VI as item(s):
5. ☒ fee calculation sheet
6. ☐ separate indications concerning deposited microorganisms
7. ☒ nucleotide and/or amino acid sequence listing (diskette)
8. ☒ other (specify): cheque; Statement to Verify

Figure No. \_\_\_\_\_ of the drawings (if any) should accompany the abstract when it is published ~~Content of Computer Readable Form~~**Box No. IX SIGNATURE OF APPLICANT OR AGENT**Submission Under  
37 C.F.R. § 1.821(f)

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

  
 Immac J. Thampoe  
 Patent Agent  
 Reg. No. 36,322

For receiving Office use only		2. Drawings: <input type="checkbox"/> received:  <input type="checkbox"/> not received:
1. Date of actual receipt of the purported international application:		
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		
4. Date of timely receipt of the required corrections under PCT Article 11(2):		
5. International Searching Authority specified by the applicant: ISA /	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid	

Date of receipt of the record copy by the International Bureau:

For International Bureau use only



# COPY

PCT INTERNATIONAL APPLICATION TRANSMITTAL LETTER	DATE 15 November 1993 (15.11.93)
REGARDING THE INTERNATIONAL APPLICATION OF BOARD OF REGENTS OF UNIVERSITY OF WASHINGTON et al.	DOCKET OR REFERENCE NUMBER B173 CIP PCT
ENTITLED PERIPHERALIZATION OF HEMATOPOIETIC STEM CELLS	

**Certification under 37 CFR 1.10 (if applicable)**

HB309709224 US

"Express Mail" mailing number

15 November 1993  
(15.11.93)

Date of Deposit

I hereby certify that this application is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

(Typed or printed name of person  
mailing application)

(Signature of person mailing  
application)

To the United States Receiving Office (RO/US):

Accompanying this transmittal letter is the above-identified International application, including a completed Request form (PCT/RO/101). Please process the application according to the provisions of the Patent Cooperation Treaty.

The following requests are made of the RO/US:

1. ☒ PREPARATION AND TRANSMITTAL OF CERTIFIED COPY OF PRIORITY DOCUMENTS—Please prepare and transmit to the International Bureau a certified copy of the United States origin priority documents identified in Box VI of the Request form (37 CFR 1.451).

To cover the cost of copy preparation and certification (37 CFR 1.19(a)(3) and (b)(1)).

- ☒ a (check) ~~amount~~ in the amount of \$ 3352.00 is attached to this transmittal letter.  
☐ the RO/US is hereby authorized to charge the following deposit account no.: (including \$12.00 for certified copy)

The appropriate Search fee for the above-named Authority is indicated on the Fee Calculation Sheet (PCT/RO/101 Annex).

2. ☐ SUPPLEMENTAL SEARCH FEES (ONLY WHEN ISA/US CONDUCTS THE INTERNATIONAL SEARCH.)—Please charge any Supplemental Search fees that may be required by the United States International Searching Authority (ISA/US) to deposit account no.: \_\_\_\_\_

*I understand that this authorization is subject to my oral confirmation thereof in each instance and that it in no way limits my right to submit a protest against payment of the Supplemental Search fees, but is merely an administrative aid to assure that the ISA/US may timely complete the Search Report.*

NOTE: SUPPLEMENTAL SEARCH FEES FOR ISA/EP ARE PAYABLE DIRECTLY TO THE EUROPEAN PATENT OFFICE

3. ☒ DISCLOSURE INFORMATION—In order to assist in screening the accompanying International application for purposes of determining whether a license for foreign transmittal should and could be granted, the following information is supplied:

A. ☐ There is no prior filed application relating to this invention. 13 November 1992

B. ☒ There is a prior application\*, serial number 07/977,702 filed on (13.11.92) which contains subject matter that is

1. ☐ substantially identical to that of the accompanying International application.  
2. ☒ less than that of the accompanying International application. The additional subject matter of the International application appears on page(s) and line(s) THROUGHOUT  
3. ☐ more than that of the accompanying International application.

C. ☐ Disclosure information cannot be covered by the language of Points 4A or 4B above due to the involvement of several prior applications or for other reasons. A separate sheet on which the disclosure information is explained is attached to this transmittal letter.

4. ☒ REQUEST FOR FOREIGN TRANSMITTAL LICENSE—According to the provisions of 35 U.S.C. 184 and 37 CFR 5.11, a license to transmit the accompanying International application to foreign agencies or international authorities is hereby requested.

\* Priority is not claimed, unless all necessary information is listed in Box VI of the Request Form (PCT/RO/101).

SIGNER IS THE

☐ APPLICANT

☐ COMMON REPRESENTATIVE

☒ ATTORNEY/AGENT

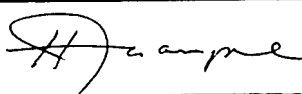
REG NO

36,322

NAME OF SIGNER (typed)

Immac J. Thampoe

SIGNATURE



# PCT

## FEE CALCULATION SHEET

### Annex to the Request

For receiving Office use only

International application No.

Applicant's or agent's  
file reference

B173 CIP PCT

Date stamp of the receiving Office

Applicant

BOARD OF REGENTS OF UNIVERSITY OF WASHINGTON et al.

#### CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE . . . . . 200. T

2. SEARCH FEE . . . . . 1512. S

International search to be carried out by EPO  
(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

##### Basic Fee

The international application contains 63 sheets.

first 30 sheets . . . . . 530. b<sub>1</sub>

33 x 10. = 330. b<sub>2</sub>

remaining sheets additional amount

Add amounts entered at b<sub>1</sub> and b<sub>2</sub>  
and enter total at B . . . . . 860. B

##### Designation Fee

6 x 128. = 768. D

number of designations amount of designation fee

(If that total exceeds the figure which corresponds to the amount of the designation fee multiplied by ten, enter the latter figure in box D.)

Add amounts entered at B and D and enter total at I . . . . . 1628. I

4. FEE FOR PRIORITY DOCUMENT . . . . . 12. P

5. TOTAL FEES PAYABLE

Add amounts entered at T, S, I and P,  
and enter total in the TOTAL box

3352.

TOTAL

☐ The designation fee is not paid at this time.

#### MODE OF PAYMENT

☒ authorization to charge  
deposit account (see below)

☐ bank draft

☐ coupons

☒ cheque

☐ cash

☐ other (specify):

☐ postal money order

☐ revenue stamps

#### DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may not be available at all receiving Offices)

The RO/ US ☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☒ is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

06-1075

15 November 1993

(15.11.93)

Deposit Account Number

Date (day/month/year)

Signature Inmac J. Thampoe